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HELLER EHRLICH LLP			EPPERSON, JON D	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	09/856,859	BATTERSBY ET AL.
	Examiner	Art Unit
	Jon D. Epperson	1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 09 March 2007.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 15-29 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 15-29 is/are rejected.
 7) Claim(s) 17 and 22 is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____.
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date _____.	6) <input type="checkbox"/> Other: _____.

DETAILED ACTION

Request for Continued Examination (RCE)

1. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/9/06 has been entered. Claims 15-29 were pending. Applicants amended claim 15. No claims were added or canceled. Therefore, claims 15-29 are still pending and examined on the merits.

Those sections of Title 35, US code, not included in the instant action can be found in previous office actions.

Withdrawn Objections/Rejections

2. All rejections are maintained and the arguments are addressed below.

Outstanding Objections and/or Rejections

Claims Rejections - 35 U.S.C. 102

3. Claims 15-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee (US Patent 4,053,433) (Date of Patent is **October 11, 1977**) as evidenced by Ravkin et al. (US 2003/0008323 A1) (Publication Date is **January 9, 2003**) and Applicants' specification. Please note: MPEP 2131.01(d) permits the citation of evidence including Applicants' specification and references in an anticipation rejection under 35 U.S.C. § 102 in order to show that a characteristic not disclosed in the reference is inherent.

For *claim 15*, Lee (see entire document) discloses methods for making and using a plurality of color-coded microparticles (e.g., see Lee, abstract; see also claims), which anticipates the claimed invention. For example Lee discloses a plurality of carriers (e.g., see Example 1 wherein the fused bundles were cut to provide a “plurality” of carriers; see also Example 2 wherein a plurality of onion microsphere carriers are produced; see also Example 4 wherein a plurality of microsandwich carriers are produced; see also abstract Summary of Invention; see also figures 1-6). Lee does not explicitly state that the plurality of different compounds “can be” synthesized on the carriers. However, the Examiner contends that this “can be” language represents mere “intended use” language or an “optional” step with regard to what is actually synthesized on the plurality of beads and thus is not afforded any patentable weight with regard to limitations that stem from the synthesis. Statements of intended use are not structural limitations that distinguish over the prior art where the prior art is capable of that use. See *In re Pearson*, 494 F.2d 1399, 1403, 181 USPQ 641, 644 (CCPA 1974); *In re Yanush*, 477 F.2d 958, 959, 177 USPQ 705, 706 (CCPA 1973); *In re Casey*, 370 F.2d 576, 580, 152 USPQ 235, 238 (CCPA 1967). For example, the use of “detectably distinct” carriers is not required by the current claims. The claims do not state that different compounds “must be” synthesized on the plurality of carriers. Rather, the claims state that a plurality of different compounds “can be” synthesized on said carriers, which renders this step optional. Thus, Applicants’ claimed carriers could contain the “same” molecules. Furthermore, Applicants’ plurality of carriers need not contain any attached molecules. Thus, codes for distinguishing “detectably distinct” carriers for “identifying” compounds

“before, during and after” synthesis is not required, as the synthesis in its entirety is entirely optional. Alternatively, the Examiner contends that this (i.e., the “can be” limitation) would be an inherent feature because Lee recognizes that said microparticles are “well suited for the tagging of … chemicals” (e.g., see column 5, lines 58-60) and Ravkin et al. explicitly state that Lee’s microparticles (referred to as “taggants”) have been used for just such a purpose (e.g., see Ravkin et al., “The invention further provides for the use of taggants [i.e., the microparticles disclosed by Lee] as coded carriers. In this embodiment, the coded carriers to which the library compounds are attached are taggant particles, such as disclosed in U.S. Pat. Nos. 4,053,433 [i.e., referring to the Lee patent]”).

In addition, Lee inherently disclose the newly added “suitable for providing a base for a sequence of reaction steps” limitation as exemplified, for example, by Applicants’ specification showing that the polyamide, polyethylene, polystyrene, polyvinyl chloride, glass beads/microspheres disclosed by Lee (e.g., see Lee column 4, line 47 wherein polyamide is disclose; see also line 66 wherein polyethylene is disclosed; see also Example 2 wherein polystyrene is disclosed; see also column 4, line 34 wherein polyvinyl chloride is disclosed) can function as a base for reaction steps as admitted by Applicants (e.g., specification, page 16, paragraph 3, “The carriers may comprise any solid material capable of providing a base for combinatorial synthesis. For example, the carriers may be polymeric supports … [including] polystyrene … porous silicates for example controlled pore-glass … polyamide … polyethylene”; see also page 20, paragraph 2, “The polymeric microparticle can be prepared from a variety of

polymerizable monomers, including styrenes, acrylates ... polyvinylchloride"). This is further supported by Ravkin et al. who explicitly state that their solid supports can participate in "a stepwise oligomer synthesis" reaction (e.g., see Ravkin et al., paragraph 54; see also paragraph 82 disclosing that the supports are chemically stable; see also paragraph 150). Lee also states that these microspheres are capable of withstanding a "dynamite blast" (see below) and thus are shown to be exceptionally stable (i.e., able to withstand any set of chemical reactions). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The Office does not have the facilities to make such a comparison and the burden is on the applicants to establish the difference. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

Furthermore, the plurality of carriers includes a population of detectably distinct carriers each having a code, which distinctively identifies a respective carrier before, during and after said synthesis from other carriers, and which is characterized by at least two detectable and/or quantifiable attributes integrally associated with the carrier (e.g., see Summary of Invention, especially, lines 34-49, "The inventory of microparticles may include up to [C][C-1n-1] uniquely coded batches [i.e., the batches are coded "before" any synthesis takes place and would not be changed or altered in any way by a chemical synthesis as exemplified by Ravkin et al. above]; see also column 5, last two paragraphs showing that said microparticles are chemically stable and can even survive a dynamite

blast; see also figures 1-6 showing at least two detectable and or quantifiable attributes such as different colors, shapes and sizes). Lee also disclose individual carriers that comprise all the attributes that define a corresponding code before commencing synthesis of a respective compound thereon (e.g., see Summary of Invention, especially column 2, lines 34-49 wherein the code is made by the colored layers “independent” of any chemical synthesis). Lee also disclose that the plurality of carries contain at least about 70% detectably distinct carriers (e.g., see Examples wherein all (i.e., 100%) of the carriers are “detectably distinct”; see also Summary of Invention, lines 34-49; see also claim 1, wherein a “unique” code is used to make “identification” and thus “all” of the plurality of carriers [i.e., 100%] are detectably distinct, that is, none of the carriers “lack a code” that would otherwise “dilute” the distinct carrier pool to less than about 70%). Finally, Lee at least two attributes where one of said attributes is not shape, or surface deformation (e.g., see figures 1-6 wherein the at least two attributes represent the at least two colored regions shown or one attribute represents color and the other attribute represents shape; please note that while Applicants’ claims preclude one of said attributes from being shape, they do not preclude the other attribute from such a designation).

For **claim 16**, Lee discloses a plurality of carriers wherein at least one of said attributes of a respective carrier is comprised within or internally of the carrier (e.g., see figures 2-4 showing attributes such as elements 28, 30, 34, 38, 40 and 42 “within” the carrier).

For **claims 17-19**, Lee discloses at least one of said attributes of a respective carrier is an electromagnetic radiation-related attribute such as light absorbance (e.g., see

Summary of Invention, column 2, lines 28-33, “The improvement in this method, according to the present invention, comprises providing microparticles which comprise compilations of, and are encoded according to, a particular orderly sequence of visually color distinguishable dyed and/or pigmented layers of organic materials”).

For **claim 20**, Lee discloses at least three detectable and/or quantifiable attributes integrally associated therewith (e.g., see Summary of Invention, lines 34-49, wherein an “eight-membered” sequence containing 12 colors per segment results in a system with 233,846,052 possible codes).

For **claim 21**, Lee discloses a fluorescent dye (e.g., see column 6, lines 17-19, “fluorescent color in the code may aid in retrieval of the microparticle”; see also column 3, lines 54-61, “The dyes and pigments used to form the colored layers or segments of the onion microsphere or the microdisc ... include ... inorganic pigments such as sulfates, chromates, sulfides, oxides, carbonates, etc., and stable organic pigments such as phthalocyanine and Hansa Yellow”).

For **claim 22**, Lee discloses, for example, “onion” and/or “microsette” particles that fall within the scope of “colloidal” particles because the finely divided pigments are “suspended” in the polymeric matrix (e.g., see Examples 1-2).

For **claim 23**, Lee discloses, various shapes including “spheres” (e.g., see figure 1).

For **claim 24**, Lee discloses different forms including “discs” (e.g., see figures 2-3).

For **claim 25**, Lee discloses different sizes (e.g., see column 3, line 37 disclosing

sizes between 50 to 200 micrometers; see also Example 2 wherein different sizes can be produced by screening a lot with No. 18, 20 and 25 American Standard screens that contain 1000, 841 and 707 micrometer openings, respectively).

For **claim 26**, Lee discloses, for example, polymeric materials (e.g., see example 2, “Microporous polymeric ion exchange resin beads (Amberlite No. A-26, a quaternary form of a polystyrene resin available from Mallinckrodt Company) about 500-750 micrometers in diameter were used as nuclei for spherical color coded microparticles, i.e., ‘onion microspheres.’”).

For **claims 27-28**, Lee discloses “glass”, which is composed of “silica” (e.g., see column 3, line 33). Lee also disclose a size that is between about 0.01 μm to about 150 μm (e.g., see column 3, lines 35-40, “... preparation of microspheres from a variety of substances in a size range preferably 50 to 200 micrometers in diameter”; see also claim 1, “microparticle being 1 to 1000 micrometers at its broadest dimension across the color sequence”).

For **claim 29**, Lee discloses, for example, “amines” and “carboxylic acids’ (e.g., see Example 2 wherein an amine is disclosed; see also column 3, line 34 wherein an albumin core is disclosed that contains an amino terminus and a carboxylic acid terminus).

Response

4. Applicant’s arguments directed to the above 35 U.S.C. § 102 rejection were fully considered (and are incorporated in their entirety herein by reference) but were not deemed

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persuasive for the following reasons. Please note that the above rejection has been modified from its original version to more clearly address applicants' newly amended and/or added claims and/or arguments.

[1] Applicants argue, “[t]he explicit terms of the claim require that a carrier be suitable for use in a series of synthetic steps and this limitation necessarily implies certain structural attributes in the carrier. For example, the carrier must be chemically suitable for coupling a compound precursor to the carrier, and must also be compatible with, and stable to, a series of synthesis steps, all while retaining the code that identifies the carrier” (e.g., see 8/9/06 Response, page 4, last 2 paragraphs).

[1] In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (e.g., “for use in a series of synthetic steps”, “chemically suitable for coupling a compound precursor to the carrier”, “compatible with, and stable to, a series of synthesis steps”) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Here, the newly amended claims merely recite that the carrier is suitable for “providing a base” for a sequence of reaction steps, not any of the limitations mentioned by Applicants above. Furthermore, no “reactions steps” are set forth in the claims which means that read on “extremely mild” conditions or a *de minimis* sequence of reaction steps. Finally, Applicants' own specification clearly sets forth that the polystyrene, polyvinyl

chloride, etc. substrates disclosed by Lee inherently make the grade (see newly amended rejection above).

[2] Applicants argue, “Nothing in Lee describes that the taggant particles are suitable for coupling of compound precursors to the particles, nor that the particles are able to withstand multiple chemical synthesis steps while retaining the color-coding present on the particles. ... Ravkin merely describes attaching the taggant particles to pre-prepared library compounds and neither explicitly nor implicitly describes, teaches or suggests synthesizing compounds directly on the taggant particles. Lee or Ravkin neither describe how the taggant particles might be used for multi-step chemical synthesis, nor provide any details that would permit the skilled artisan to understand that the taggants could be used for this purpose. To this end it is notable that Example 1 of Ravkin describes (with no experimental detail) that pre-synthesized oligonucleotides were attached to taggant particles and states that the purported experiments show that ‘DNA can be linked to taggant carriers.’ This further demonstrates that Ravkin is merely using taggant particles of the type described by Lee as labels for pre-synthesized molecules, rather than using the particles as bases for multi-step synthesis. The fact that a certain result or characteristic occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic ... Inherency may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient ... Applicants respectfully submit that the Examiner has failed to show that the taggant particles described by Lee necessarily have the properties recited in the instant claims and therefore respectfully request that the rejection be withdrawn.” (e.g., see 8/9/06 Response, pages 4 and 5).

[2] Again, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (e.g., "suitable for coupling of compound precursors to the particles," "particles are able to withstand multiple chemical synthesis steps while retaining the color-coding present on the particles", etc.) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Here, the newly amended claims merely recite that the carrier is suitable for "providing a base" for a sequence of reaction steps, not any of the limitations mentioned by Applicants above. Furthermore, no "reactions steps" are set forth in the claims which means that read on "extremely mild" conditions or a *de minimis* sequence of reaction steps. In addition, Applicants' own specification clearly sets forth that the polystyrene, polyvinyl chloride, etc. substrates disclosed by Lee inherently make the grade (see newly amended rejection above).

The Examiner also contends that Applicants' reading of Ravkin is too narrow. For example, Ravkin explicitly state that their solid supports can be used in multiple synthetic reaction steps (e.g., see Ravkin, paragraph 54, "The carriers placed in each reaction vessel may each be formed ... [via] stepwise oligomer synthesis [i.e., suitable for coupling of compound precursors such as oligomers to the particles]"; see also paragraph 87, "The code on a carrier is more permanent because the code exists through the structure and therefore is not susceptible to change as a result of chemical synthesis [i.e., i.e., the particles are able to withstand multiple chemical synthesis steps while retaining he color-coding present on the particles]"; see also paragraph 150, "The carriers are prepared according to known methods to act as the support

surface for stepwise solid-phase synthesis"). Thus, Applicants' narrow interpretation of the Ravkin reference is unjustified. Example 2 is merely just that i.e., an example. Applicants cannot limit the scope of the teaching of Ravkin to a single example.

Finally, with regard to Applicants' argument that a limitation must "necessarily" flow from the reference the Examiner notes that the Courts do permit a "reasonable" amount of "speculation" to determine whether said result and/or characteristic would necessarily occur. For example, in *In re Best* (e.g., see *In re Best*, 195 USPQ 430 (CCPA 1977)) the Court upheld an anticipatory reference under the doctrine of inherency even though it was not clear whether the claimed "cooling step" necessarily flowed from the prior art reference. The claims in *Best* were drawn to a process for stabilizing zeolites from which sodium cations had been removed by ion exchange and further required a "cooling step" that was not expressly recited by the prior art. However, the Court held that this cooling step was inherently disclosed even though it did not "necessarily" flow from the reference. For example, the zeolites in the anticipatory reference could have been handled with gloves while they were hot, avoiding said cooling step. Thus, the Court permitted the Examiner to "speculate" as to the temperature at which the zeolites were handled (i.e., room temperature), which then permitted the Court to deduce that a cooling step "necessarily" occurred based on this speculation. In the present case, it is reasonable to speculate that the carriers disclosed by Lee will "necessarily" be suitable for providing a base for a sequence of reaction steps" for the reasons set forth in the newly amended rejection above. Furthermore, the "reaction step" have not bee specified and the means by which the carriers are supposed to "function as a base" have also not been specified. Thus, the claims are still broad in scope and would encompass virtually any solid support. "When the PTO shows a sound basis

for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The Office does not have the facilities to make such a comparison and the burden is on the applicants to establish the difference. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

Accordingly, the 35 U.S.C. §102(b) rejection cited above is hereby maintained.

New Rejections

Objections to the Claims

5. Claims 17 and 22 are objected to because of the following informalities:
 - A. Claims 17 and 22 are objected to be cause it recites a “plurality of carrier” instead of the proper “plurality of carriers.” Appropriate correction is requested.

Claim Rejections - 35 USC § 112, second paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
7. Claim 15-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- A. **Claim 15** recites the limitation "the synthesis" in the last fiver. There is

insufficient antecedent basis for this limitation in the claim. Although line 2 reads that compounds “can be” synthesized when this step is considered to be “optional” (i.e., “can be” = “optional”) then no prior recitation of a synthesis is set forth. Therefore, claim 15 and all dependent claims are rejected under 35 USC 112, second paragraph.

B. For **claim 24**, the term “hollow fiber needle” is vague and indefinite. For example, the specification sets forth a hollow fib[ers] or needles but not a composite “hollow fiber needle” as set forth inc claim 24. Applicants are requested to clarify and/or correct. Therefore, claim 24 and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.

C. For **claim 24**, the phrase “electromagnetic radiation-related attribute ... comprises a fluorescent dye” is vague and indefinite because an attribute (i.e., a physiochemical property such fluorescence, luminescence, etc. set forth in claim 18) is not a tangible entity (i.e., a dye molecule). Applicants are requested to clarify and/or correct.

Therefore, claim 21 and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 15-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

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skilled in the relevant art that the inventor(s), at the time the application was filed had possession of the claimed invention. This is a new matter rejection.

A. Claim 15 was amended in the 8/9/06 response. However, applicants cited passages did not show were support for the newly added limitation, "wherein each carrier is suitable for providing a base for a sequence of reaction steps." If applicant believes this rejection is in error, applicant must disclose where in the specification support for this amendment can be found (page and line number) in accordance with MPEP 714.02.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (571) 272-0808. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon D. Epperson, Ph.D.
May 27, 2007

JON EPPERSON
PRIMARY EXAMINER

